MAR 2 8 2014

K130263

510(k) Summary

Applicant's Name, Address, Telephone, FAX, Contact Person
Advanced Sterilization Products, Division of Ethicon, Inc.
a Johnson & Johnson company
33 Technology Drive
Irvine, CA 92618

Contact Person
Nancy Chu
Manager, Regulatory Affairs
Tel: (949) 453-6435
Fax: (949) 789-3900

SUMMARY DATE
February 26, 2014

1. CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name:	Biological Sterilization Process Indicator
Common/Usual Name:	Biological Indicator (Test Pack)
Product Classification:	Class II
Product Code:	FRC
Panel:	General Hospital
Classification Regulation:	21 CFR 880.2800
Proprietary Name:	STERRAD® 50/100S/200 Test Pack

2. PREDICATE DEVICES

- STERRAD® CycleSure® Test Pack (K051643, cleared August 19, 2005)
- STERRAD® 100NX® Test Pack (K071537, cleared December 18, 2007)

3. INDICATIONS FOR USE

The STERRAD® 50/100S/200 Test Pack is used for routine monitoring of the STERRAD® 50, STERRAD® 100S and STERRAD® 200 Sterilizers and is also used for the periodic testing of these sterilizers using hospital-defined loads containing devices that do not exceed claims of the cycle.

The STERRAD® 50/100S/200 Test Pack consists of the following components:

- STERRAD® CYCLESURE® 24 Biological Indicator (REF 14324)
- Test Pack vial with "STERRAD® 50/100S/200" marking and a corresponding cap
- STERRAD® Instrument Mats (REF 99205)
- Tyvek® Pouch with STERRAD® Chemical Indicator (REF 12340)

4. DESCRIPTION OF DEVICE

The STERRAD® 50/100S/200 Test Pack consists of a pouch which holds a closed vial containing a STERRAD® CYCLESURE® 24 Biological Indicator (BI) and silicon mats. The vial and its corresponding cap have defined orifices.

5. SUMMARY OF NONCLINICAL TESTS

The STERRAD® 50/100S/200 Test Pack has been evaluated for its resistance to the STERRAD® 100S, 50, and 200 Sterilizers.

A comparison of the STERRAD® 50/100S/200 Test Pack to the biological model developed for their respective cycles indicates that the Test Pack is at least as resistant to the sterilization process as the biological model. This is based on both survival curves and fraction negative data as a function of dose.

STERRAD® 50/100S/200 Test Packs assembled from three lots of CYCLESURE® 24 Biological Indicator (BI) were exposed to several doses of hydrogen peroxide in STERRAD® 100S, STERRAD®50, or STERRAD® 200 Cycles. These survivor curves were compared to the survivor curves for the biological model developed for the respective cycles. The test data showed that the Test Pack configuration was at least as resistant as the biological model.

Additionally, fraction negative data were collected using Test Packs assembled from three lots of CYCLESURE® 24 BI and exposed to increasing volumes of hydrogen peroxide in

STERRAD® 100S, STERRAD®50, or STERRAD® 200 Cycles. The results indicated that the Test Pack configuration was at least as resistant as the biological model.

Indicative functionality of the chemical indicator in a STERRAD® 50/100S/200 Test Pack configuration was evaluated using half-cycle parameters of the STERRAD® 100S, STERRAD®50, and STERRAD® 200 Cycles and was determined to be appropriate for a chemical indicator.

The subject device and its predicate device have the same intended use which is for routine monitoring of the STERRAD® 100S, STERRAD®50, or STERRAD® 200 Cycles. Additionally, they have the same technological characteristics, the same operating principles and are subjected to the same sterilant (hydrogen peroxide) and therefore, the subject device is substantially equivalent to the predicate. A comparison of similarities and differences of design features and materials of construction and Indications for Use of both the subject and two predicate devices are shown in Table 1 and Table 2, respectively.

Table 1: Comparison of Similarities and Differences between Devices

	Subject Device	**Predicate Device (K051643)**	**Predicate Device (K071537)**
Name	STERRAD® 50/100S/200 Test Pack	STERRAD® CycleSure® Test Pack	STERRAD® 100NX® Test Pack
Cycle	For use in STERRAD® 50, STERRAD® 100S or STERRAD® 200 cycle	For use in STERRAD® 50, STERRAD® 100S or STERRAD® 200 cycle	For use in STERRAD® 100NX® Standard or Flex cycle
Biological Indicator	STERRAD® CYCLESURE® 24 Biological Indicator	STERRAD® CYCLESURE® 24 Biological Indicator	STERRAD® CYCLESURE® 24 Biological Indicator
Tyvek Pouch	Tyvek Pouch, 8"x16"	• Tyvek Pouch, 3" x 8" • Tyvek Pouch, 6" x 12.5"	Tyvek Pouch, 6" x 12.5"
Test Pack Vial	• Test Pack Vial with an opening (1.40 to 1.55 mm) in the center of the bottom; 17 mm x 52 mm • High density polyethylene (HDPE)	• Test Vial has an opening (1.3 ± 0.20 mm diameter) in the center of the bottom; 27 mm x 61 mm • High density polyethylene (HDPE)	• Test Pack Vial, with no opening in the bottom; 17 mm x 52 mm • High density polyethylene (HDPE)

	Subject Device	Predicate Device (K051643)	Predicate Device (K071537)
Test Vial Cap	• Test Vial Cap with an opening (1.40 to 1.55 mm) in its center; diameter of 18 mm • High density polyethylene (HDPE)	• Cap has an opening (1.3 ± 0.20 mm diameter) in the center; diameter of 22 mm • High density polyethylene (HDPE)	• Test Vial Cap with an opening (1.40 to 1.55 mm) in its center; diameter of 18 mm • High density polyethylene (HDPE)
STERRAD® Sterilization Mat	Four mats, 2.5" x 6.5"	Two mats, 2.5" x 6.5"	Four mats, 2.5" x 6.5"

Table 2: Comparison of Indications for Use between Devices

Device	Name	Indications for Use Statement
Subject Device	STERRAD® 50/100S/200 Test Pack	The STERRAD® 50/100S/200 Test Pack is used for routine monitoring of the STERRAD® 50, STERRAD® 100S and STERRAD® 200 Sterilizers and is also used for the periodic testing of these sterilizers using hospital-defined loads containing devices that do not exceed claims of the cycle. The STERRAD® 50/100S/200 Test Pack consists of the following components: • STERRAD® CYCLESURE® 24 Biological Indicator (REF 14324) • Test Pack vial with "STERRAD® 50/100S/200" marking and a corresponding cap • STERRAD® Instrument Mats (REF 99205) • Tyvek® Pouch with STERRAD® Chemical Indicator (REF 12340)
Predicate Device (K051643)	STERRAD® CycleSure® Test Pack	The STERRAD® Sterilizer CycleSure® Test Pack is used for routine monitoring of the STERRAD® 50, STERRAD® 100S and STERRAD® 200 Sterilizers and is also used for the periodic testing of these sterilizers using hospital-defined loads.

Device	Name	Indications for Use Statement
Predicate Device (K071537)	STERRAD® 100NX® Test Pack	The STERRAD® 100NX® Test Pack is used for routine monitoring of the STERRAD® 100NX® sterilization cycle and is also used for the periodic testing of a STERRAD® 100NX® system using hospital-defined loads.

Table 3 below lists the tests performed to demonstrate that the STERRAD® 50/100S/200 Test Pack functions as intended in the STERRAD® 100S, STERRAD®50, or STERRAD® 200 Cycle.

Table 3: Testing Summary

Studies Performed	Results
Design Evaluation and Performance Qualification of STERRAD® 50/100S/200 Test Pack in the STERRAD® 50 Sterilizer	Passed
Design Evaluation and Performance Qualification of STERRAD® 50/100S/200 Test Pack in the STERRAD® 100S Sterilizer	Passed
Design Evaluation and Performance Qualification of STERRAD® 50/100S/200 Test Pack in the STERRAD® 200 Sterilizer	Passed
Functionality Study of the Chemical Indicator Disc of CYCLESURE® 24 BI in Test Pack	Passed
Functional Compatibility Testing of STERRAD® Test Pack Reusable Components	Passed

6. OVERALL PERFORMANCE CONCLUSIONS

The performance data shows that the STERRAD® 50/100S/200 Test Pack has the necessary resistance relative to the biological model to be an appropriate challenge for testing the STERRAD® 100S, STERRAD® 50 and STERRAD® 200 Sterilizer, and it is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 28, 2014

Advanced Sterilization Products
Ms. Nancy Chu
Manager, Regulatory Affairs
33 Technology Drive
Irvine, CA 92618

Re: K130263
Trade/Device Name: STERRAD® 50/100s/200 Test Pack
Regulation Number: 21 CFR 880.2800
Regulation Name: Biological Indicator (Test Pack)
Regulatory Class: II
Product Code: FRC
Dated: February 26, 2014
Received: February 27, 2014

Dear Ms. Chu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

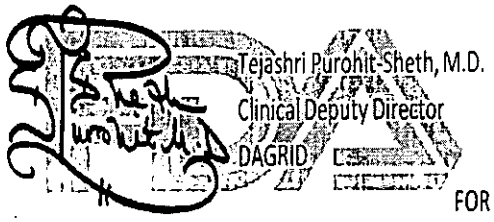
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K130263

Device Name
STERRAD® 50/100S/200 Test Pack

Indications for Use *(Describe)*

The STERRAD® 50/100S/200 Test Pack is used for routine monitoring of the STERRAD® 50, STERRAD® 100S and STERRAD® 200 Sterilizers and is also used for the periodic testing of these sterilizers using hospital-defined loads containing devices that do not exceed claims of the cycle.

The STERRAD® 50/100S/200 Test Pack consists of the following components:
- STERRAD® CYCLESURE® 24 Biological Indicator (REF 14324)
- Test Pack vial with "STERRAD® 50/100S/200" marking and a corresponding cap
- STERRAD® Instrument Mats (REF 99205)
- Tyvek® Pouch with STERRAD® Chemical Indicator (REF 12340)

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth F. Claverie -S
2014.03.24 16:39:24 -04'00'